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Background

This supplement was developed by the Dr. Robert Bree Collaborative (Bree Collaborative) and the Washington Agency Medical Directors' Group (AMDG) in collaboration with an advisory group of the state's academic pain leaders, pain experts, providers in primary care and specialty areas, addiction medicine experts, and patients. The supplement updates the evidence and aligns best practice recommendations with those from the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, guidelines from the HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, and the Washington State Administrative Code (WAC) pain rules. Recommendations are based on current best available clinical and scientific evidence from the literature and a consensus of expert opinion and are intended for use in addition to, rather than a replacement of, the guidelines for treating patients on chronic opioid therapy in the 2015 AMDG guidelines.

Recommendations are intended for providers managing adult patients (>18 years old) with chronic pain who are receiving long-term opioid therapy. These guidelines do not apply to (1) treatment of patients with cancer-related pain; (2) provision of palliative, hospice, or other end-of-life care; (3) treatment of inpatient hospital patients who have been admitted for more than twenty-four hours; or (4) provision of procedural medications. See WAC 246-817-905, 246-840-463, 246-853-661, 246-919-852 or 246-922-661 for further definitions. Providers managing patients on long-term opioid therapy should start with patient engagement followed by thorough assessment and careful deliberation regarding an appropriate treatment pathway. Management should be individualized and should focus, in addition to reducing the intensity of pain, on goals of improving function and quality of life, and optimizing patient independence, while avoiding serious adverse outcomes. Recommendations are organized into:

- Establishing a relationship: patient engagement
- Assessment
- Developing a treatment plan
 - Maintain and Monitor
 - Reduce Dosage
 - Transition to Medications for opioid use disorder (MOUD)
- Recommendations for Health Plans and Health Delivery Systems

Guiding principles for systematically addressing, to the extent possible, every patient on long-term opioid therapy should follow those laid out by the National Pain Strategy and be:

- Patient-centered, accounting for individual preferences, risks, and social contexts
- Comprehensive, meeting biopsychosocial needs
- · Multimodal and integrated, using evidence-based treatments

Additionally, delivery systems should follow the 2019 Bree <u>Collaborative Care for Chronic Pain Report</u> <u>and Recommendations</u> that outline a chronic pain management model within primary care. The model includes a team with care coordination function, multi-modal treatments based in evidence-informed care, and patient-centered self-management tools.

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Establishing a relationship: patient engagement

Every person's experience of pain is unique. The development of a trusting relationship and honest communication between a provider and patient is foundational to the successful management of chronic pain, particularly when a change in the treatment plan might be indicated.¹ Taking the time to understand the role chronic pain plays in a person's life and what impacts it has on work, relationships and social activities is an important part of successful patient engagement and the development of a trusting relationship. As each person's circumstance is unique, chronic pain management, should always be individualized.^{2,3}

- **Discuss goals of care**. (e.g., "what are your expectations?", "what do you hope to accomplish?", "what meaningful parts of your life are you currently missing out on?"). Work to understand the social and emotional dynamics that may impact chronic pain management. Goals are about things patients want to do (e.g., walk around the block). Having a goal discussion helps you get to know the patient as a person, demonstrates you care about their individual experience, and provides a basis for future conversations.
 - Clarify "bigger picture" or life goals and short-term goals driven by longer-term goals. Short-term goals should be specific, measurable, achievable, relevant and time-bound (SMART).⁵ This framework can be helpful for reframing conversations and promoting behavior change. Information on setting SMART goals can be found here.
- **Set expectations**. Assure the patient that your **goal is to keep them safe while maximizing function**. 6,7,8 The first visit should be used to develop rapport and begin a thorough assessment.
 - Talk about realistic expectations around pain (e.g., that becoming pain free is unlikely).
 - Make sure the patient knows who to contact with questions or concerns.
 - Assure the patient that you will act as a partner with them and support continuity of their care, unless patient- or provider-specific factors prohibit effective partnership.
- Gain an understanding of the patient's knowledge about pain and their current medication(s), educate on knowledge gaps. Discuss current medication purpose, how medications work, and potential side effects. 910 Talk about chronic pain treatment approaches outside of chronic opioid therapy. Discuss any fear or concern around pain, abandonment, stigma, and safety. Understand that fear of pain may be more meaningful to a patient than risk of overdose. 11
 - Use the teach-back method to ensure that a patient understands complicated or new information.¹² Information from the Agency for Healthcare Research and Quality on the teach-back method is here.
- Engage and educate others, where appropriate. Ask if the patient's spouse, parents, children or others could be included in the discussion of any treatment plan. Social support has been shown to be a facilitator to effective chronic pain management. Understand concerns from family and others. See Appendix C: Questions for Family Members.
- **Respect.** Treat patients with respect and address and validate concerns in a non-judgmental manner.
- Consistency. Use consistent messaging from all team members and in all visits.
- Cultural competency. Assure that interactions with patients are culturally humble. 13

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Assessment

Assessment of patients on long-term opioid therapy will likely require a structured and a staged approach over several visits. Assessments should be non-judgmental, de-stigmatizing, and collaborative. Brief screening instruments can inform the assessment, and should not replace clinical observation and judgment. The following elements should be part of the assessment:

- Patient history. Complete a detailed, appropriate medical history including conditions and
 associated treatment from personal interview as well as by reviewing medical records. Note the
 pain related diagnosis, including documentation of the presence of one or more recognized
 indications for the use of pain medication.
 - o The nature and intensity of the pain.
 - Location of pain(s). This can be documented using a pictorial representation of the body,
 fill in all the parts of the body affected by chronic pain.
 - o Review the nature and intensity of withdrawal symptoms, if experienced.
 - o The effect of pain on physical and psychosocial function;
 - Current and relevant past treatments for pain, including opioids and other medications and their efficacy; and
 - Document history of long-term opioid use from the first prescription, as accurately as possible. Include dosage and changes in dosage over time.
 - Document pain-related interventions, including spine and extremity surgery, injections, any integrative health interventions and impact on pain and function.
 - Review and document the current treatment agreement if one is in place.
 - Document other medications including prescribed and over the counter.
 - Assess opioid-related adverse outcomes and significant side effects. See Medical Risks of Long-Term Opioid Use table.
 - o Review any pertinent diagnostic, therapeutic, and laboratory results
 - Review any pertinent consultations
- Observation of the patient's affect and behavior. Interviewing a family member or caregiver
 may reveal problems or benefits otherwise missed. Documenting this type of information may
 be important in accurately assessing the patient's physical and psychosocial functioning on
 opioids and successfully implementing treatment pathways (See Treatment).
- Physical exam. Perform an appropriate physical exam, including a detailed examination of all
 pain-related regions; for patients with neuropathic pain of any kind, document a detailed
 neurological examination.
- Pain and functional status. Use a validated tool such as the PEG (Pain intensity, interference
 with Enjoyment of life, and interference with General activity) scale. To the extent possible,
 from medical records and from patient self-report, estimate functional improvement in
 response to opioids.
- Prescription Monitoring Program. Review the PMP to identify any medications received by the patient in accordance with the provisions of WAC 246-817-980, 246-840-4990, 246-853-790, 246-919-985 or 246-922-790. Document all findings relevant to controlled substance use, including concomitant opioid and sedative, multiple opioid prescribers, and early refills.

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- **Urine drug test (UDT).** Administer urine drug screening. Unexpected results require discussion with the patient and if necessary, confirmation testing. For further guidance on UDT, see Appendix D in the 2015 AMDG Opioid Guideline.
- Review comorbidities with particular attention to psychiatric and substance use. Obtain a complete history of alcohol and other substance use. Follow the 2017 Bree Collaborative Behavioral Health Integration Report and Recommendations, 2018 Bree Collaborative Suicide Care Report and Recommendations, and 2015 Bree Collaborative Addiction and Dependence Treatment Report and Recommendations. Use validated instrument(s) to screen for co-occurring conditions that can influence the experience and intensity of chronic pain:
 - o **Depression** (e.g. Patient Health Questionnaire-2, PHQ-3 and/or PHQ-9)
 - Anxiety (e.g., Generalized Anxiety Disorder-2)
 - Suicidality (e.g. ninth question of the PHQ-9, first and second questions of the Columbia Suicide Severity Rating Scale (C-SSRS), the Ask Suicide-Screening Questions (ASQ) as well as current plans and any past attempts).
 - Post-traumatic stress disorder (e.g. PTSD Checklist)
 - Adverse childhood experiences. More information here.
 - Alcohol misuse (e.g., AUDIT-C)
 - Substance use (e.g., single-item screener, ASSIST, DAST-10, single item cannabis and other drug use questions).
- Use a validated tool to determine the patient's level of risk for opioid or other substance use disorders as high-, moderate-, or low-risk category or use a two-tier tool.
- **Evaluate for opioid use disorder.** If there are indications of opioid misuse, or concomitant illicit opioid use, evaluate the patient for the presence of an opioid use disorder.
 - See Appendix X DSM-5 criteria for diagnosis of Opioid Use Disorder.
 - Tolerance and withdrawal are expected physiologic phenomena associated with chronic opioid use. The physical symptoms of withdrawal occur with the cessation of opioids prescribed for chronic use in individuals in pain and in persons who have an opioid use disorder. Their presence alone does not define the presence of an opioid use disorder or addiction
- **Health record.** This information may be used to supplement the assessment. Risk of opioid overdose and problematic opioid use increases with the number of factors present as follows:
 - Long-term opioid therapy daily dose >50/90 MED
 - Use of extended release/long acting opioids
 - Any use of sedatives/benzodiazepines
 - Chronic use of sedatives/benzodiazepines
 - Opioid use disorder diagnosis
 - o Non-opioid alcohol use, tobacco use, or drug use disorder diagnosis
 - Other behavioral health disorder diagnosis add specific diagnoses (?)

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Develop a Treatment Plan

Treatment plans should be developed in collaboration with the patient, and family or others if appropriate. See Appendix X for a flow chart showing treatment options after assessment. Determine together whether to stay on opioids, reduce opioid dose at a rate consistent with patient's clinical and social situation, or transition to medications for opioid use disorder (MAT). Patients may want to stop chronic opioid therapy due to a variety of reasons, including lack of efficacy, side effects, impact on quality of life, and concerns about addiction. In determining a treatment pathway, clinicians and patients may have divergent priorities. While providers may be most concerned about overdose or addiction, many patients may consider that they personally may have low risk of serious adverse outcomes. Patients are more likely to fear pain, suffering, and loss of control more than a serious event. However, patients also are likely to have priorities for effective pain treatment beyond simple pain relief, including wanting better emotional wellbeing, improved physical activity, better sleep, and greater social participation.

One method for achieving consensus is the use of motivational interviewing. This approach involves "expressing empathy and avoiding arguing, developing discrepancy, rolling with resistance, and supporting self-efficacy (client's belief s/he can successfully make a change)." The goal of motivational interviewing is understanding the patient's motivations and barriers to change in order to change a behavior such as with smoking cessation.

Exercise professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist as outlined in WAC 246-817-908, 246-840-4653, 246-853-680, 246-919-910 or 246-922-680. Ideally, chronic pain should be managed through a collaborative care model as described in the 2019 Bree Collaborative Care for Chronic Pain Report and Recommendations. These guidelines focus on the use of a care team to achieve goals of improved function, increased quality of life, and greater patient autonomy, rather than a primary focus on pain relief. However, this system-supported modality is not available in all areas and should not preclude high-quality chronic pain management and the following of these recommendations.

Develop a treatment plan in collaboration with the patient:

- Counsel patients, including discussion of opioid-related risks and safe storage and disposal. See
 WAC 246-817-907, 246-840-4651, 246-853-675, 246-919-865 or 246-922-675.
- Document any medication prescribed, biologic specimen testing ordered, any labs, diagnostic evaluations, referrals, or imaging ordered, and other planned treatments.
- Involve behavioral health providers, where possible.² Pain alone does not cause depression, anxiety, or alcohol use disorder, although it can exacerbate these conditions. In addition, patients may experience anxiety or fear associated with changes in treatment approach. Useful language includes:
 - These providers are here to help you through these changes.
 - Opioids are effective at suppressing symptoms of anxiety and post-traumatic stress disorder.
 - Difficulty with sleeping makes everything worse.

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- Some patients feel anger, shame, grief, or questioning whether life has meaning or purpose.
- **Use non-opioid pharmacological pain management**. This can include acetaminophen, non-steroidal anti-inflammatory drugs, topicals (e.g., capsaicin, lidocaine, diclofenac), anticonvulsants, intermittent steroid injections, serotonin/norepinephrine reuptake inhibitors, and others as indicated.
- **Use non-pharmacological pain management**. Identify, support and enhance what patients are already doing to manage chronic pain with life activity impacts. Discuss:
 - Cognitive-behavioral therapy
 - Mindfulness
 - o Exercise and body awareness strategies (e.g. yoga, tai chi, qigong)
 - Manual therapies (e.g., massage, spinal manipulation)
 - Acupuncture
 - Reactivation methods (e.g., physical therapy, activity coaching)
 - Multidisciplinary rehabilitation
- Use a treatment agreement that includes all the necessary rule requirements. See WAC 246-817-930, 246-840-475, 246-853-725, 246-919-915 or 244-922-725.

In light of the above assessment, and in collaboration with the patient, where possible, decide whether to maintain and monitor the current opioid regimen, taper, or wean off long-term opioids following the 2019 HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, or transition to medications for opioid use disorder if opioid use disorder is present.

- Maintain and Monitor.
 - Consider this pathway for patients meeting the following criteria:
 - No history of non-fatal overdose or other serious adverse events
 - Not on combinations of opioids and sedatives
 - No significant side effects that impair function and impact quality of life
 - Opioids are not principally prescribed for a centralized pain condition (e.g., nonspecific musculoskeletal disorder, fibromyalgia, headaches)
 - No recent history (i.e., five years) of alcohol misuse or illicit substance use
 - No history of opioid misuse or diversion
 - No unexpected controlled substances on PMP or unexpected results from UDT
 - No history of requesting early refills or history of lost or stolen medication
 - Opioid prescribing is consistent with WAC
 - Periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries as well as the content of the review should follow WAC 246-817-935, 246-840-477, 246-853-730, 246-919-985 or 246-922-730.
 - For a high-risk patient, at least quarterly;
 - For a moderate-risk patient, at least semiannually;
 - For a low-risk patient, at least annually;
 - Immediately upon indication of concerning aberrant behavior; and
 - More frequently at the physician's discretion.
 - Tapering or discontinuation.

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- Consider tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy by following the 2019 HHS Guide for Clinicians on the
 Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics (more detailed information available on the link above)
 - Pain-generating condition resolved
 - The patient requests dosage reduction or discontinuation
 - Pain and function are not meaningfully improved
 - The patient is receiving higher opioid doses without evidence of benefit from the higher dose
 - The patient has current evidence of opioid misuse
 - The patient experiences side effects that diminish quality of life or impair function
 - The patient experiences an overdose or other serious event (e.g., hospitalization, injury) or has warning signs for an impending event such as confusion, sedation, or slurred speech
 - The patient is receiving medications (e.g., benzodiazepines) or has medical conditions (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for adverse outcomes
 - The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear
- Follow tapering flowchart outlined in the 2019 HHS guidelines. The rate of taper should be individualized. When opioid dosage is reduced, a taper slow enough to minimize opioid withdrawal symptoms and signs should be used. Tapering plans should be individualized based on patient goals and concerns. The longer the duration of previous opioid therapy, the longer the taper may take.
 - Slower tapers (e.g., 10% per month or slower) are often better tolerated than more rapid tapers, especially following opioid use for more than a year. Longer intervals between dose reductions allow patients to adjust to a new dose before the next reduction. Tapers can be completed over several months to years depending on the opioid dose.
 - Faster tapers can be appropriate for some patients. A decrease of 10% of the original dose per week or slower (until 30% of the original dose is reached, followed by a weekly decrease of 10% of the remaining dose) is less likely to trigger withdrawal and can be successful for some patients, particularly after opioid use for weeks to months rather than years.
 - More rapid tapers (e.g., over 2-3 weeks) might be needed for patient safety when the risks of continuing the opioid outweigh the risks of a rapid taper (e.g., in the case of a severe adverse event such as overdose).
 - Ultra-rapid detoxification under anesthesia is associated with substantial risks and should not be used.
 - At times, tapers might have to be paused and restarted again when the
 patient is ready. Pauses may allow the patient time to acquire new skills
 for management of pain and emotional distress, introduction of new

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- medications, or initiation of other treatments, while allowing for physical adjustment to a new dosage.
- Tapers may be considered successful as long as the patient is making progress, however slowly, towards a goal of reaching a safer dose, or if the dose is reduced to the minimal dose needed.
- Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped, if appropriate, when taken less often than once a day.
- Treat symptoms of opioid withdrawal.
- Provide behavioral health support.
- Medications for opioid use disorder. Refer to the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, Part VI (Recognition and Treatment of opioid use disorder):
 - In many cases, a clear diagnosis of opioid use disorder using DSM-5 criteria may not be apparent. Failed attempts at tapering, or persistent and severe withdrawal symptoms in spite of best medical treatment to address these symptoms, or failed multidisciplinary treatment for chronic pain, may indicate the need for a trial of MAT.
 - Use evidence-based therapy including medications for opioid use disorder if opioid use disorder is present. Follow the 2017 Bree Collaborative <u>Opioid Use Disorder Treatment Report and Recommendations</u> and the <u>2015 Agency Medical Directors Guideline on Prescribing Opioids for Pain Part VI Recognition and Treatment of opioid use disorder.</u>
 - Buprenorphine. Once a patient is having mild-to-moderate withdrawal, administer 2 to 4 mg of sublingual buprenorphine or buprenorphine plus naloxone. If patient has no unacceptable side effects, administer an additional 4–8 mg sublingually at 1–2 hours, followed by adjustment according to response up to 32 mg daily in divided doses
 - For those on buprenorphine, patients must abstain from short acting opioid agonists for at least 8 to 12 hours (best accomplished overnight; a longer interval is usually required for long acting opioids or fentanyl) and be in mild-to-moderate withdrawal (a score of ≥8 on the Clinical Opiate Withdrawal Scale)
 - Methadone. Referral if indicated.
 - Naltrexone. Requires full withdrawal off opioids for 7-10 days.

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Health System Recommendations

The CDC chronic opioid guidelines, in addition to advocating for more cautious opioid prescribing by primary care providers, also call for payment and delivery system reform to align with and support these efforts. Specifically, the guidelines call for "strengthened coverage for non-pharmacologic treatments, appropriate urine drug testing, and medications for opioid use disorder; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care."

Primary care providers on the frontlines of the opioid epidemic need support from health plans and health systems. Infrastructure to support best-practice care is critical to the success and sustainability of primary care providers to assess, address, and help patients on long-term therapy. This section makes recommendations for health care systems and health plans to support and elevate the unique education, training, and experience of primary care providers so they can better meet the complex needs of patients on long-term therapy.

Health Plans

Health plans should follow guidelines in the Collaborative Care for Chronic Pain recommendations including for reimbursement for collaborative care programs. Additionally, health plans should:

- Expand reimbursement for Structured Intensive Multidisciplinary Programs (SIMP) to increase
 access and availability when medically necessary. Quality measures and expectations for SIMP
 should also be developed to support and coincide with these efforts.
- Develop payment models that fairly reimburse for the time and effort required to assess patients on chronic opioid therapy. The full evaluation may take several hours, which is not accounted for by any current E/M codes.

Health Care Systems

Health care systems should follow guidelines in the Collaborative Care for Chronic Pain recommendations including for access to collaborative care programs, identifying chronic pain patients, and developing a multidisciplinary team that may include pharmacists and nurse care managers, and others. Additionally, health care systems should:

- Train staff on motivational interviewing.
- Consider creating a SIMP at the health care system or collaborating with one to ensure access to
 intensive, multimodal treatment options when indicated. This can be a helpful venue for
 patients being tapered off opioids.
- Academic Detailing. Academic detailing can offer support to primary care providers to help gain confidence in managing patients on chronic opioid therapy. These one-on-one conversations with a senior clinician can offer general knowledge on related principles as well as guidance and validation on challenging cases. Data from the registry can help facilitate these discussions.
- **Hub and spoke**. Hub and spoke models for opioid use disorder treatment can expand access to opioid agonist therapy and also offer support and guidance to primary care providers managing patients with addiction.

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Medical schools and residency training programs should improve education and training on pain management and recognition of substance use disorder. Formal curriculums should be adopted on these topics. Johns Hopkins University has developed a state-of-the-art <u>four-day course</u> for medical students on pain. In particular, health care providers and future health care providers would benefit from enhanced education and training on:

- Factors that influence pain
- The role of nonpharmacological therapy in the treatment of chronic pain and research supporting its use
- The role of self-management in the treatment of chronic pain
- Engagement and communication strategies for patients with chronic pain and patients on chronic opioids
- Assessing the risks and benefits of chronic opioid therapy
- Various risk mitigation strategies, their indications, interpreting results, and discussing those results with patients
- Having difficult conversations with patients and saying "No"
- Recognition and treatment of substance use disorder

Organized medicine and academic medical centers should also emphasize the above in training providers. The American Medical Association has published an <u>educational module</u> to help teach these principles to primary care providers and implement them into primary care practice. Additionally, academic detailing should be operationalized in large health care systems to give providers additional support and training on these issues in real time.

Other Stakeholders

- The Centers for Disease Control and Prevention should develop better epidemiological tools to monitor and detect the emergence of opioid use disorder and suicidality in patients on chronic opioids.
- Departments of Health should determine statewide policies for addressing patients on chronic opioid therapy when the prescribing provider retires or leaves practices for other reasons.
- Federal and State agencies should look internally to ensure consistency amongst policy and regulations. Agencies should work collaboratively with one another to ensure consistency between regulations with the goal of mitigating mixed messages for the medical community and minimizing unintended consequences.
- Health and Human Services and the Drug Enforcement Administration should remove barriers to buprenorphine prescribing and expand access to buprenorphine prescribing and provide clarification on perceived barriers to opioid use disorder treatment.

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Evidence

Engagement

Additional components of successful patient engagement in chronic pain care include discussing goals of care and preferences, setting expectations, understanding individual patient needs and talking about concerns and fears around pain and treatment. ^{16,17,18,19} The positive effect of goals of care discussions are well-documented and should be considered early. ^{20,21,22}

Assessment

The PEG assessment should be done at each visit.²³ General reviews of factors to consider in the assessment of patients with chronic pain include the importance of a thorough history and an interview where the patient's behavior can be observed.¹ At a systems level, state Prescription Drug Programs have some of the best evidence on beneficial impact on prevention.²

Use of screening instruments, urine drug test, or patient treatment agreements to determine risk of overdose, misuse, or development of opioid use disorder among patients on chronic opioid therapy (COT) has been recommended but not proven in studies to be strongly predictive of improved outcomes. Earlier reviews have not demonstrated, for example, that use of urine drug test or implementation of a patient treatment agreement can meaningfully improve patient outcomes.^{3,4} In a system wide study in Group Health Cooperative, overdose risk was not abated by a large risk reduction initiative.⁵

A large VA Health system cohort study identified risk factors obtained from administrative data most likely to be associated with either prescription opioid overdose or serious opioid-induced respiratory depression.⁶ The highest risk subgroups most commonly included factors such as diagnosis of opioid dependence, >/= 100 mg/day MED, ED visits or hospitalizations, use of any extended release or long-acting opioid formulations, and opioid doses between 50-<100 mg/day MED. Information obtained from electronic health records (EHR)) using natural language processing may supplement a search for ICD diagnostic terms in the medical record that can help identify problematic opioid use among patients on chronic opioid therapy.⁷ Among over 22,000 patients on COT in a large health system, 10% were found to have traditional ICD codes indicating problematic opioid use, and another third (about 3%) were identified using EHR derived data.⁷

More recently, the concept of refractory dependence or complex, persistent opioid dependence has has been suggested as a diagnosis for patients who exhibit both physical and emotional symptoms from withdrawal of prolonged opioid use, but who do not fully meet the criteria for opioid use disorder.⁸

Treatment Pathways

Substantially more evidence on tapering has been published since the literature review on the 2015 AMDG guideline was completed in December 2014.

Frank et al (2017), using GRADE methodology, conducted a systematic review of 67 studies, including 11 randomized trials.²⁴ The review concluded that, based on very low quality of evidence, several interventions may be effective at promoting tapering, and pain, function, and quality of life may improve with tapering. The strongest evidence with fair-good studies included interdisciplinary programs with mean opioid discontinuation rates of 87% and behavioral interventions, with mean opioid discontinuation rates of 21%. Very weak studies included buprenorphine dose reduction and ketamine-assisted dose reduction. The authors concluded that 1) education for patients on long-term

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opioid therapy should include the message that pain severity, function, and quality of life may improve after opioid tapering, 2) there should be consideration of referral to a multidisciplinary, multimodal pain program to support opioid dose reduction, and 3) team-based strategies with close follow-up to support opioid tapering when multidisciplinary programs are not available.

Berna et al (2015) conducted a comprehensive review of 117 articles and offered recommendations for everyday practice targeted at primary care physicians.²⁵ An overarching conclusion was that discontinuing long-term opioid therapy is most often hindered by patients' psychiatric co-morbidities and under-developed coping skills, as well as a lack of formal guidelines for prescribers to successfully taper. Several issues pointed out by Berna et al (2015) provide additional potential guidance: 1) Immediately following a successful taper of COAT, or after discontinuing post-op opioids, sensory hyperalgesia may occur, 2) the potential utility of use of objective and subjective opiate withdrawal scales (Clinical Opiate Withdrawal Scale [COWS]; Subjective Opiate Withdrawal Scale [SOWS]), 3) Overall, aggregating patients across numerous studies, patients report improvements in function without associated worsening in pain (N=1007) or even decreased pain levels (N=513), 4) Patients who take opioids only intermittently (<once daily) do not need a formal taper, 5) Empirical protocols since the 1990s favor tapers using the patient's long term opioid treatment medication, vs switching to another medication for the taper, 6) psychological support may be needed to address possible anxiety related to the taper, underlying depression, and deficient pain- and stress-coping strategies, 7) A taper agreement, including a collaboratively formulated plan, may help foster an effective therapeutic relationship and minimize the risk of breaking trust, 8) in patients with opioid dependence, buprenorphine may reverse opioid-induced hyperalgesia and reduce opioid tolerance. Convincing evidence from 8 studies (aggregated N=14,224), including 3 randomized clinical trials and a large openlabel observational study, supports the benefits of this practice.

Several recent randomized trials of tapering have been reported since 2015; they have in common difficulty in recruitment or high drop-out rates, emphasizing the importance of patient and provider engagement in any tapering program. Sullivan et al reported a 22 week randomized controlled trial with opioid taper support vs usual care (N=35).²⁶ Although this study did not achieve significant differences in opioid dose reduction or pain severity ratings between the supported group vs the usual care group, self-reported pain interference and pain self-efficacy were improved in the intervention group. This was essentially a feasibility study to launch a larger funded study now underway.

In an observational study at a single pain clinic at Stanford University, Darnall et al (2018) reported that 75% of eligible patients on COAT (82/110) volunteered to enter a tapering protocol.²⁷ Patients were followed for 4 months (completers) on a slow taper, with only education (a self-help book) and physician support, but no behavioral intervention; 38% (31/82) of enrolled patients did not complete the four month end-date survey and were considered drop outs. Among completers, baseline opioid dose (median dose =288 MED/day) was reduced to a median of 150 mg MED. Dose reduction was not associated with worse pain intensity or pain interference. Duration of opioid use did not predict taper success. Thus, even patients on very high doses followed closely in a pain clinic may be willing to at least initiate a taper protocol.

Frank et al conducted key informant interviews among 24 Colorado patients who were currently on COAT and had not tried tapering (6/24, 25%), were currently tapering (12/24, 50%), or who had discontinued COAT (6/24, 25%).²⁸ Patients perceived a low risk of overdose and a higher and more immediate risk of increased pain with tapering. Fear of withdrawal and a perceived lack of effectiveness of non-opioid options were identified as barriers. Social support and a trusted health care provider to

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facilitate tapering were identified as helpful among those with tapering experience. Improved quality of life was reported following successful tapering. Another qualitative study on a small number of patients emphasized the individualized nature of communications regarding possible tapering and emphasized assuring patients they would not be abandoned. (Matthias et al, 2017)²⁹

Evidence on taper speed is almost entirely based on studies of patients with opioid use disorder related to heroin use (not chronic pain). Consensus opinions on taper speed range from 5-10% every 2-4 weeks to 2-10% every 4-8 weeks, with pauses as needed.³⁰ Veterans Administration recommendations are for 5-20% every 4 weeks. Detailed example tapers are also offered.³¹ Sudden discontinuation is strongly NOT recommended. A cohort study from Vermont Medicaid, in whom discontinuation occurred in a median of 1 day, indicated that most patients either had no taper or rapid taper. Forty-nine percent of these patients had an opioid related hospitalization or emergency department visit subsequent to the sudden or rapid discontinuation. A majority (60%) of these Medicaid recipients had a diagnosed substance use disorder prior to tapering, and <1% had been transitioned onto an OUD medication.³² On April 9, 2019 the FDA published a Drug Safety Communication strongly advising against abrupt discontinuation among patients on long-term opioid therapy.³³

Studies published to date have not been designed to evaluate effects of tapering on overdose risk, use of illicit opioids, or suicidality/suicide events. Research is needed on effectiveness of adjunctive treatments; buprenorphine taper in the context of chronic pain with or without prescription opioid taper; speed of taper; and the effects of patient and clinical factors on taper outcomes. More research is also needed evaluating tapering in primary care and the health systems support necessary for effective tapering in primary care. Multiple randomized trials of interventions to promote opioid taper are underway.

Treatment pathway-Treat for Opioid Use Disorder

Medications for opioid use disorder has been shown to improve outcomes for people with opioid use disorder.³⁴ Often medication is combined with behavioral therapy (e.g., counseling) for a whole-person approach, augmenting behavioral therapy alone and has been shown to be more effective than behavioral therapies, medically-supervised withdrawal, or abstinence alone.^{35,36,37}

Health Systems Interventions

Use of the **Six Building Blocks**, as originally devised for chronic disease management at Group Health Cooperative of WA, and expanded by work at the MacColl Institute, has been recently applied to assist primary care practitioners in safety net clinics, such as Federally Qualified Health Centers, to improve management of patients on long-term opioid therapy. The Bree Collaborative Care model for Chronic Pain) follows the principals of the Six Building Blocks. Use of telecare to deliver collaborative management is an emerging area.³⁸ In this model, lower intensity intervention can be delivered by a pharmacist care manager.

Delivery of **multimodal pain care** in the community has the most evidence in randomized controlled trials for the effective treatment for chronic musculoskeletal pain, one of the most important contributors to years lived with disability in the US (Murray et al)³⁹

A **peer support specialist** has been used in the Southern Oregon Pain Guidance effort to assist the patient on COT throughout, including as a teacher/mentor, as a tapering and withdrawal coach, as an

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advocate, and as a resource purveyor, for example, with available community resources. The peer support specialist has also worked with providers on difficult conversation training.

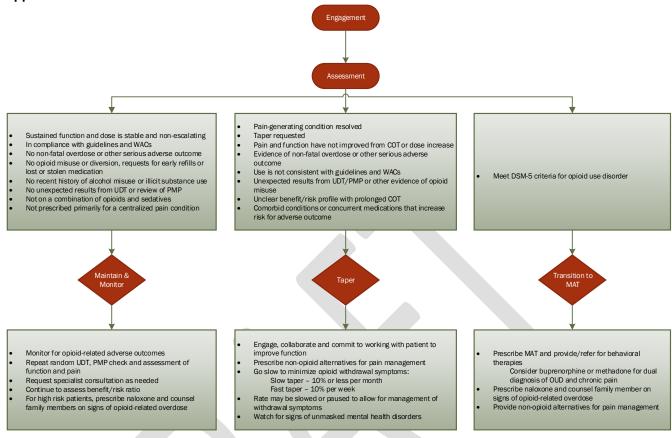
Institutional multidisciplinary panel support for primary care practitioners to assist with the care and assessment of patients on COT has been employed at Veterans Administration health Centers in Portland and New Haven. The Department of Labor and Industries in now exploring similar types of support mechanisms through its Centers for Occupational Health and Education. 404142

The **Vermont Hub and spoke model**, also being explored in Washington's Accountable Communities of Health, has been applied to the care of patients with opioid use disorder, but it could also be deployed to assist in the more complex phases of care for the patient on COT, particularly those with more severe dependence or OUD.

Multidisciplinary pain clinics have been used at the University of California-San Francisco, Cleveland Clinic, the Mayo Clinic, and by the WA Department of Labor and Industries, to assist with prescription opioid tapering.

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Appendix X: Treatment Flowchart



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Appendix X: Tables from 2015 AMDG

Table 8. When to Reduce, Taper, or Discontinue COAT

Patient requests opioid taper.

Patient is maintained on opioids for at least 3 months, and there is no sustained clinically meaningful improvement in function (<u>CMIF</u>), as measured by validated instruments (<u>Appendix B: Validated Tools for Screening and Assessment</u>)

Patient's risk from continued treatment outweighs the benefit (e.g. decreased function and increased risk for opioid-related toxicity from concurrent drug therapy or comorbid medical conditions)

Patient has experienced a severe adverse outcome or overdose event

Patient has a substance use disorder (except tobacco)

Use of opioids is not in compliance with DOH's pain management rules or consistent with the AMDG Guideline

Patient exhibits aberrant behaviors (Table 9)

Table 9. Aberrant Behaviors

Less suggestive for addiction but are increased in depressed patients	More suggestive of addiction and are more prevalent in patients with substance use disorder
 Frequent requests for early refills; claiming lost or stolen prescriptions Opioid(s) used more frequently, or at higher doses than prescribed Using opioids to treat non-pain symptoms Borrowing or hoarding opioids Using alcohol or tobacco to relieve pain Requesting more or specific opioids Recurring emergency room visits for pain Concerns expressed by family member(s) Unexpected drug test results Inconsistencies in the patient's history 	 Buying opioids on the street; stealing or selling drugs Multiple prescribers ("doctor shopping") Trading sex for opioids Using illicit drugs, +UDT for illicit drugs Forging prescriptions Aggressive demand for opioids Injecting oral/topical opioids Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.)

Adapted from Passik, S. 2006

Table 10. Symptoms and Treatment of Opioid Abstinence Syndrome (withdrawal)

Restlessness, sweating or tremors	Clonidine 0.1-0.2 mg orally every 6 hours or transdermal patch 0.1-0.2 mg weekly (If using the patch, oral medication may be needed for the first 72 hours) during taper. Monitor for significant hypotension and anticholinergic side effects.
Nausea	Anti-emetics such as ondansetron or prochlorperazine
Diarrhea	Loperamide or anti-spasmodics such as dicyclomine
Muscle pain, neuropathic pain or myoclonus	NSAIDs, gabapentin or muscle relaxants such as cyclobenzaprine, tizanidine or methocarbamol
Insomnia	Sedating antidepressants (e.g. nortriptyline 25 mg at bedtime or mirtazapine 15 mg at bedtime or trazodone 50 mg at bedtime). Do not use benzodiazepines or sedative-hypnotics.

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Appendix X: Questions for Family Members

- How can I best support my family member?
- What should I do if I see their well-being deteriorate?
- How can I best advocate for my family member?
- What are some red flags I should watch for related to the chronic pain in my family member?
 - Mental health concerns (Depression, Anxiety, Suicide)
 - Reduced functionality
 - Isolation
- Opioids are increasing my family member's function and quality of life. Will that continue?
- If opioids stop working or my family member's health goes downhill, what do I do?
- Are there additional therapies they can try?
- What safety issues should I watch for?
 - o Misuse, Addiction, Overdose, Diversion, Withdrawal
 - o Help them keep their pill log
 - Help them track side effects
 - Watch for over sedation
 - Lock up the meds and don't tell others you have them.
 - Know the signs of addiction
 - o Know the signs of withdrawal. This will happen if your spouse misses a dose.
- When is my spouse going to get better?
- How can I help him?
- Are the opioids making him better or worse?
- How can I tell if he is becoming dependent or addicted?
- I am worried about having opioids in my house. What can I do to make sure these are safely stored?

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Appendix X: Substance Use Disorder Questionnaire

The following brief simple questions can be used to inquire about substance misuse. Any use of an illegal drug or use of a prescription drug for a non-medical reason indicates increased risk of opioid overdose and opioid use disorder.

•	•	ast year have you used an illegal drug or used a prescription edical reasons?
Never □] Once	More than once □
IF MALE under	age 65, A	sk:
In the past yea	ar, how ma	any times have you had 5 or more drinks in a day?
ı	Never 🗆	Once ☐ More than once ☐
IF FEMALE or o	over age 65	5, Ask:
8B. In the past	year, how	many times have you had 4 or more drinks \ in a day?
ı	Never □	Once More than once
Have you more unable to do so		e tried to give up or cut down on your use of opioid pain medicines and been
No		Yes
Have you ever	felt a stror	ng urge or desire to take opioid pain medicines?
No		Yes □
Have you ever their use?	continued	to use opioid pain medicines despite emotional or physical problems related to
No		Yes

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Appendix X: Medical Risks of Long-Term Opioid Use

Long-term opioid use can cause diverse adverse effects that differ across patients. A brief, simple information sheet like that shown above can be used with patients to review common medical risks of opioids to identify problems that patients may not realize are being caused by their use of opioid analgesics, while educating patients about opioid-related risks.

Reference: Baldini A, Von Korff M, Lin EHB. A review of potential adverse effects of long-term opioid therapy: A practioner's guide. The Primary Care Companion for CNS Disorders 2012; 14(3): pii: PCC.11m01326.

Medical Risks of Long-term Opioid Use



viedical Risks of Long	-term Opioid Us	se Grouphealtr
Medical risk	How common?	Description and information
Respiratory depression		
Opioid overdose	< 1% per year but increases with dose	Caused by severely slowed breathing, which you may not notice Severe cases are treated in the hospital Can cause death
Breathing problems during sleep	Not known	- Opioids may cause or worsen sleep apnea - You may not notice breathing problems
njuries		
Falls & fractures	Not known	
Motor vehicle crashes	Not known	
Gastrointestinal problems		
Constipation	30 - 40%	 It helps to use stool-softeners or drugs that stimulate bowel movements
Serious intestinal blockage	<1% per year	Caused by severe constipation Severe cases are treated in the hospital
lormonal effects		
Hypogonadism, impotence, infertility,	25% - 75%	- Hypogonadism = lowered sex hormones, which can worsen sexual function
osteoporosis		- Osteoporosis can make you more likely to fracture or break a bone
Cognitive and neurophysiologic effects		
Sedation	15%	- Can cause difficulty driving or thinking clearly
Disruption of sleep	Not known	
Hyperalgesia	Not known	- Hyperalgesia = being more sensitive to pain
sychosocial		
Depression, anxiety, de- activation, apathy	Not known	 Depression can worsen pain, while pain can worsen depression. Opioids can cause loss of interest in usual activities, which can increase depression.
Addiction, misuse, and diversion	5 - 30%	 Common signs of prescription opioid addiction are preoccupation with opioid use or craving, unsuccessful attempts to discontinue use or cl down, cutting down or giving up activities due opioid use, and using more medication than prescribed.
Oral Health		
Dry mouth that may sometimes cause tooth decay	Dry mouth is common	Brush your teeth and rinse your mouth often Chew sugarless gum and drink water or sugar free, non-carbonated fluids
Myoclonus	Not Known	- Myoclonus = muscle twitching

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Appendix X: DSM-V Criteria for Opioid Use Disorder

e croeria rici considered to	VIA* be met for those individuals taking opicids solely under appropriate medical supervision.
eck all that app	oly
	Opioids are often taken in larger amounts or over a longer period of time than intended.
	There is a persistent desire or unsuccessful efforts to cut down or control opioid
	use.
	A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
	Craving, or a strong desire to use opioids.
	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
	Continued opioid use despite having persistent or recurrent social or
	interpersonal problems caused or exacerbated by the effects of opioids.
	Important social, occupational or recreational activities are given up or reduced
	because of opioid use.
	Recurrent opioid use in situations in which it is physically hazardous
	Continued use despite knowledge of having a persistent or recurrent physical or
	psychological problem that is likely to have been caused or exacerbated by
	opioids. *Tolerance, as defined by either of the following:
	The state of the s
	 (a)a need for markedly increased amounts of opioids to achieve intoxication or desired effect
	(b)markedly diminished effect with continued use of the same amount of an
	opioid
	*Withdrawal, as manifested by either of the following:
	(a) the characteristic opioid withdrawal syndrome
	(b)the same (or a closely related) substance are taken to relieve or avoid
	withdrawal symptoms

Severity: Mild: 2-3 symptoms. Moderate: 4-5 symptoms. Severe: 6 or more symptoms



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Appendix X: 2015 Agency Medical Directors Guideline

Reasons to Discontinue COAT and Considerations Prior to Taper

- Consider tapering patients in an outpatient setting if they are not on high dose opioids or
 do not have comorbid substance use disorder or an active mental health disorder, as this
 can be done safely and they are at low risk for failing to complete the taper.
- Seek consultation from a pain management specialist or Structured Intensive
 Multidisciplinary Pain Program (SIMP; described in Non-opioid Options) for patients who
 have failed taper in an outpatient setting or who are at greater risk for failure due to
 high dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or
 any active mental health disorder. If SIMP is not available, engage patients in activities
 that emulate the biopsychosocial approach of such a program. Rarely, inpatient
 management of withdrawal may be necessary.
- Refer patients with aberrant behaviors (Table 9) for evaluation and treatment.

How to Discontinue Opioids

- Consider sequential tapers for patients who are on chronic benzodiazepines and opioids.
 Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
- Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).
- Establish the rate of taper based on safety considerations: a. Immediate discontinuation if there is diversion or non-medical use, b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or c. Slow taper for patients with no acute safety concerns. Start with a taper of ≤10% of the original dose per week and assess the patient's functional and pain status at each visit
- Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms (Table 10).
- Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions (Appendix B: Validated Tools for Screening and Assessment).
- Consider the following factors when making a decision to continue, pause or discontinue the taper plan: a. Assess the patient behaviors that may be suggestive of a substance use disorder b. Address increased pain with use of non-opioid options. c. Evaluate patient for mental health disorders. d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is CMIF, reduced pain and no serious adverse outcomes.
- Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.

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- Increase the taper rate when opioid doses reach a low level (e.g. (e.g. <15 mg/day MED), since formulations of opioids may not be available to allow smaller decreases.
- Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome
 (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms
 are rarely medically serious, although they may be extremely unpleasant. Symptoms of
 mild opioid withdrawal may persist for six months after opioids have been discontinued
 (Table 10).
- Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
- Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use.
- Consider inpatient withdrawal management if the taper is poorly tolerated.



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Appendix X: Future Research Direction

Our understanding of pain and of how to most effectively treat pain continues to grow. Some experts believe that in addition to the previous assessment elements, the definition of opioid dependence should be expanded to describe both the physical and negative emotional symptoms that occur with withdrawal from prolonged opioid use, a concept not reflected in either the DSM-IV or DSM-V. This "complex, persistent" dependence is not the same as opioid use disorder or addiction. While the neural changes that lead to complex, persistent dependence are similar to those seen in persons with addiction, persons with "complex, persistent" dependence do not exhibit the full range of behaviors that define opioid use disorder, though some overlap may occur. This condition is not apparent until the patient is weaned off opioids and the symptoms persist. Characteristics of this 'complex, persistent' dependence can include any/all of the following characteristics:

- No uncontrollable craving or compulsive use
- o No harmful use that is not medically directed (patient takes opioid exactly as prescribed)
- Withdrawal drug opposite effects: somatic withdrawal symptoms, hyperalgesia, hyperkatefeia, dysphoria
- Potential difficulty tapering
- Stress-like symptoms

Reward deficiency (i.e. anhedonia or difficulty experiencing pleasure in life) and social withdrawal Future research will help to clairify these ideas and ideally guide treatment if this condition is found to be part of the clinical spectrum of pain and treatment responses.

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